

JUDGE BRICCETTI

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

17 CV 7781

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STANLEY KOSHY

Plaintiff,

-against-

REGENERON PHARMACEUTICALS, INC.

Defendant.
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: Civil Action No.

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:
: **COMPLAINT**

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:
: ECF CASE

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:
: PLAINTIFF DEMANDS
: **A TRIAL BY JURY**

Plaintiff Stanley Koshy (“Koshy” or “plaintiff”), by his attorneys, Ianniello Anderson, P.C., complaining of defendant Regeneron Pharmaceuticals, Inc. (“Regeneron”) or (“defendant”) alleges as follows:

NATURE OF THE ACTION

1. This action is brought by plaintiff seeking damages and other relief for Defendants’ violations of the anti-retaliation provisions of the Federal False Claims Act, 31 U.S.C. § 3730 (h)(1) (“FCA”) and New York Labor Law § 740 (“NYLL 740”).

2. Plaintiff seeks declaratory relief, back pay, front pay, interest, compensatory damages, punitive damages, attorney’s fees, costs and other appropriate legal and equitable relief pursuant to the FCA and the NYLL.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 28 U.S.C. § 1337.

4. The Court has supplemental jurisdiction over the state law claim pursuant to 28 U.S.C. § 1367(a).

5. Venue is appropriate in the Southern District of New York pursuant to 28 U.S.C. § 1391 (b) and 1391 (c) because the defendant is located in this District and the defendant does business in this District.

THE PARTIES

6. Stanley Koshy (“Koshy”) is a resident of East Brunswick, New Jersey.

7. At all relevant times, Koshy was employed by defendant within the meaning of the False Claims Act, 31 U.S.C. § 3730(h).

8. At all relevant times, Koshy was an employee of defendant as defined by the New York Labor Law § 740.

9. Regeneron Pharmaceuticals, Inc. has a principal place of business, executive offices and facilities at 777 Old Saw Mill River Road Tarrytown, NY 10591.

10. Upon information and belief, Regeneron is a science-based biopharmaceutical company that discovers, invents, develops, manufactures and commercializes medicines for the treatment of serious medical conditions.

11. Upon information and belief, Regeneron commercializes medicines for eye diseases, high LDL cholesterol, a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis, atopic dermatitis, asthma, pain, cancer and infectious diseases.

FACTUAL ALLEGATIONS

Koshy’s Employment with Regeneron

12. Koshy commenced work as the Manager of Contract Manufacturing Organization (CMO) Strategic Relationships on or about May 2, 2016.

13. As the Manager of CMO Relationships, Koshy was to strategically manage business relationships and coordinate day to day operations with CMO sites to achieve a consistently high level of interaction to meet or exceed Regeneron's business needs relating to product quality, availability and delivery.

14. Koshy's essential duties and responsibilities included, but were not limited to, serving as the primary liaison between Regeneron Industrial Operations and Product Supply and contract manufacturers or business partners, coordinating all manufacturing activities at contract and/or business partner sites, resolving all supply issues with the CMO that affect product quality or availability, upholding product integrity and company reputation by assisting in the monitoring of current good manufacturing practice ("cGMP") compliance at CMO sites, helping to drive appropriate corrective or preventive actions and providing regulatory filing support when needed.

15. Throughout his employment at Regeneron Plaintiff performed satisfactorily and either met or exceeded Defendants' reasonable business expectations.

Koshy's Protected Activity

16. During Koshy's employment he discovered numerous issues regarding CMO sites and brought each to the attention of his supervisor and project managers.

Koshy Complained That Requisite Change Controls Were Not In Place At Cook Pharmica CMO

17. On June 4, 2016, at a meeting with QA Supply Chain, Regulatory and other team members regarding the requirement for quality documentation, Koshy expressed concerns regarding a major specification change in the level or colony forming unit ("CFU") of acceptable bioburden (viable bacteria or fungus cell) that was implemented at the Cook Pharmica CMO in August 2015 without requisite change control in place. Specifically, Regeneron

implemented new requirements concerning the maximum level of bioburden in clinical trials to 10 CFU/100ml from 1CFU/10ml.

18. At the June 4, 2016 meeting Koshy was asked to implement major specification changes in the level of CFU acceptable bioburden for other CMOs without requisite change controls in place. Koshy questioned the impact of the implementation at Cook Pharmica and requested that moving forward change controls be in put in place. Without requisite change controls in place, Koshy expressed that there was a risk of false negative bioburden tests or approval of a batch of product with unacceptable levels of bioburden causes inaccurate documentation to be submitted to the FDA and also creates a substantial and specific danger to the public health and safety and could lead to patient fatalities.

19. Upon information and belief, Regeneron receives federal monies for drugs that are manufactured at CMO sites.

20. Pursuant to regulation and company policy a “major change” is one that causes regulatory impact, or a change which may alter the quality, identity, strength, potency, safety and/or efficacy of the manufactured product.

21. Pursuant to company policy, as well as requirements of regulatory bodies, including the FDA, change controls are required to identify the impact of change, from old specification to new specification and the pharmaceutical product’s purity, safety and efficacy.

22. After the June 4, 2016 meeting, Koshy in writing and verbally expressed concerns to his supervisor James Jackson about the major changes implemented at Cook Pharmica and the lack of change controls and received no response.

Koshy Complained That Corrective and Preventive Action Not In Place At Cook Pharmica CMO

23. In late June 2016, Koshy visited the Cook, Indiana CMO and discovered

that revised instructions provided by Regeneron to the CMO regarding the production of REGN 668 (“Dupixent”) were not executed pursuant to 21 CFR Sec. 211.103 (written procedures deviation). The lot was filled using two BDS lots instead of one as specified in the revised allocation sent to the CMO by Regeneron. This means that there was a system failure for possible cross-contamination that could result in a substantial and specific danger to the public health and safety. In addition, there is risk that fraudulent documentation would be sent to the FDA.

24. After Koshy’s discovery of this issue a team meeting was held at Regeneron on June 30, 2016. At the meeting Koshy expressed concerns regarding the lack of corrective and prevention action (“CAPA”). The law requires that each drug manufacturer have CAPA procedures. Koshy also wrote at least twice to the project managers and his supervisor James Jackson regarding the issue, asking for deviation notification and corrective and preventive action. These were never implemented.

25. Upon information and belief, in February 2017, the FDA issued citations to Cook Pharmica regarding the same issues that Koshy complained to Regeneron about including the drug manufacturer’s testing procedures, lack of contamination safeguards and computer systems validations. The FDA specifically found that the firm disregarded its procedures aimed at preventing microbial contamination. The FDA also cited Cook Pharmica because its laboratory controls lacked testing procedures to assure all in-process materials met the quality standards.

Koshy Complains Regarding Supply Chain Gap Analysis

26. On or about July 7, 2016, Koshy responded to an email string regarding

supply chain gap analysis which is done to identify gaps in the approval and release of supplier components which interface with the drug product during fill operation at CMO sites. A lack of adequate testing by CMOs or an absence of a certificate of compliance by suppliers can lead to product contamination. Koshy expressed his concerns to his supervisor about this issue and sent him an article regarding a past recall of Johnson and Johnson Children's Tylenol due to factory conditions where the company was fined approximately \$25M by the FDA for not following quality controls and not maintaining adequate lab facilities for the testing and approval of components and drug products. Koshy was concerned that without adequate systems in place, a bad product could end up out on the market and create a substantial and specific danger to the public health and safety.

27. In September 2016, the FDA issued a first observation letter to Regeneron regarding gaps in approval of suppliers by Regeneron.

Koshy Complains Regarding Shipment of Rejected Product

28. In or around early July 2016, Koshy had a disagreement with project manager John Fredericks regarding the shipment of rejected (excessive bioburden) product Eylea from Par Pharmaceutical in Michigan to Sharp Packaging in Illinois. Koshy opposed the shipment because of public safety and accountability. There were reports made of missing product from the same site. Koshy also brought these issues in an email to the attention of the QA supervisor, Trisha Bowie, as well as to his supervisor James Jackson. A couple of days later, John Fredericks went to Koshy's office and stated that he wanted to choke him.

29. Late in July, 2016 during a presentation meeting regarding CMO sites, John Fredericks stated he wanted to punch Koshy in the nose. This presentation included a plan to improve safety, quality and efficiency at select CMO sites, including Cook Pharmica.

Koshy's Involvement on the Zika Virus Project

30. During his employment at Regeneron, Koshy was also assigned to a project involving a preclinical program targeting the Zika virus. Upon information and belief, Regeneron received funding from the U.S. Department of Health and Human Services ("HHS") for this project.

31. In light of the other issues relating to lack of requisite change controls and corrective and preventive action, Koshy expressed concerns that procedures be followed on the Zika project.

32. Koshy received documentation from colleagues at Regeneron complimenting his work on the Zika Virus project.

Koshy is Retaliated Against Because of His Protected Activity and Ultimately Terminated From Employment with Regeneron

33. On July 29, 2016, Koshy met with HR and his supervisor, James Jackson and Paul Hainsworth and was presented with an employee warning for allegedly acting unprofessionally at a company training session in June 2016. Koshy vehemently disagreed with this statement.

34. The next day on Saturday, July 30, 2016, Koshy sent a short email to the CEO alleging that he felt he was being retaliated against.

35. On July 31, 2016, Koshy was notified by HR at around 8:30pm not to report to work the next day.

36. On Monday, August 1, 2016, Koshy sent another email to the CEO outlining his concerns and providing a summary of the meeting with HR.

37. On August 4, 2016, Koshy again met with HR and his supervisor James

Jackson who stated at this meeting that he felt Koshy needed to be disciplined. Koshy again relayed his concerns that procedures were not being followed related to rejected products.

38. Koshy was not disciplined or provided any warning letter subsequent to the August 4, 2016 meeting and was returned to work August 11, 2016.

39. Later in August James Jackson removed Koshy from the Zika Virus project without any explanation.

40. Then in September 2016 James Jackson announced that John Fredericks (project manager) would be taking on additional responsibilities which should have been assigned to Koshy pursuant to his job description and duties.

41. Koshy sent an email to his supervisor, James Jackson asking for an explanation related to the changes in his work duties, but did not receive any response.

42. In early October, 2016, Koshy sent another email to the CEO regarding the retaliation he felt he was experiencing from James Jackson.

43. Koshy was terminated from employment on October 11, 2016.

CAUSE OF ACTION
(Violation of FCA)

44. Plaintiff repeats and re-alleges each and every allegation set forth in the preceding paragraphs, as if fully set forth herein.

45. Plaintiff brings this Cause of Action pursuant to the anti-retaliation provisions of the False Claims Act, 31 U.S.C. § 3730(h).

46. Plaintiff engaged in protected activity under the FCA.

47. By the above actions and omissions Defendant has violated the FCA, by discriminating and retaliating against Plaintiff in the terms and conditions of his employment including the decision to terminate Plaintiff's employment.

48. Defendant knew or suspected, actually or constructively, that the employee engaged in protected activity.

49. Defendant terminated Plaintiff in violation of FCA because Plaintiff engaged in protected activity.

50. Defendant acted intentionally and with malice and/or reckless indifference to Complainant's federally protected rights.

51. Plaintiff has been unable despite reasonable efforts to find comparable employment.

52. Plaintiff suffered monetary damages, including lost wages, as well as mental anguish and humiliation as a result of Respondent's discriminatory practices.

CAUSE OF ACTION
(Violation of NYLL § 740)

53. Plaintiff repeats and realleges the above paragraphs as if fully set forth herein.

54. Defendant was prohibited from taking retaliatory personnel action against Plaintiff for his disclosure to his supervisor of the activity, policy, or practice of his former employer that was in violation of law, rule, or regulation which violation creates and presents a substantial and specific danger to public health or safety and for objecting to and refusing to participate in any such activity, policy or practice.

55. Defendant terminated Plaintiff because Plaintiff reported incidents to Regeneron and objected to and refused to participate in the employer's unlawful policies and practices.

56. Plaintiff has been unable, despite reasonable efforts, to find comparable employment.

57. As a result of the foregoing, plaintiff has been denied employment; has lost wages, benefits, and promotional opportunities; and has incurred damages thereby.

PRAYER FOR RELIEF

WHEREFORE, plaintiff respectfully requests an Order and Determination, pursuant to Federal False Claims Act, 31 U.S.C. § 3730 (h)(1) (“FCA”) and New York Labor Law § 740 (“NYLL 740”).

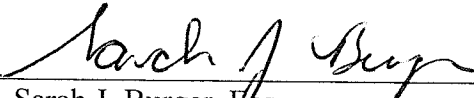
- a. declaring that the acts and practices complained of herein are in violation of the FCA and the NYLL;
- b. preliminarily and permanently enjoining these violations of the FCA and the NYLL;
- c. directing defendant to place plaintiff in the position he would have continued to occupy but for defendant’s discriminatory treatment of him, and make him whole for all earnings he would have received but for defendant’s discriminatory treatment, including, but not limited to, wages, bonuses, pension and other lost benefits;
- d. directing defendant to pay plaintiff compensatory damages for his mental anguish and humiliation;
- e. directing defendant to pay plaintiff punitive damages for its intentional disregard or and/or reckless indifference to plaintiff’s statutory rights;
- f. awarding plaintiff any costs of this action together with reasonable attorneys’ fees;
- g. awarding such further relief as is deemed necessary and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, plaintiff demands a trial by jury in this action.

DATED: October 6, 2017

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